

K962851

SEP - 6 1996

510(k) Summary

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Date of preparation: July 15, 1996

Device Name (proprietary): AcryNoodles™ Absorbent Wound Dressing

Common Name: Moist wound dressing

Classification Name: Hydrogel wound dressing

Classification: Unclassified; as recommended by the General and Plastic Surgery Devices Panel 79

Legally marketed device(s) for substantial equivalence comparison:

AcryDerm Advanced Wound Dressing, (AcryMed, Inc.)

Kaltostat Wound Dressing, (Calgon Vestal Laboratories)

AquaFlo Hydrogel Wound Dressing/Packer, (Sherwood Medical Co.)

Description of Device: AcryNoodles Absorbent Wound Dressing (AcryNoodles™) is a moist wound dressing for external use that is composed of a hydrophilic absorbent matrix processed into a bundled strand format. AcryNoodles will be supplied in the following sizes: 5-1/2" x 3/4"; 5-1/2" x 1-1/2"; 5-1/2" x 3"; and 10" x 10-1/2" all with cross-sectional strand dimensions of 0.05 x 0.05". AcryNoodles will be supplied sterile, packaged as an individual bundle, in heat sealed medical grade form-vac blister packs with product information applied to the flat surfaced peelable cover. Primaries will be packed, with Instructions For Use, 5 primaries per intermediate carton, and 10 intermediate cartons per case. Biocompatibility has been established according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

Intended Use of the Device: AcryNoodles is intended as an external wound dressing for use in the management of exudate from chronic wounds such as pressure sores, arterial ulcers, diabetic ulcers, and venous stasis ulcers and acute wounds such as draining surgical wounds, lacerations, donor site, and exuding first and second degree burns, and abrasions. It is not intended for use on third degree burns.

Technological Characteristics: AcryNoodles Absorbent Wound Dressing is composed of an unsupported synthetic polyacrylate hydrogel. It carries the same general classification name, "Hydrogel", as AcryDerm Advanced Wound Dressing and AquaFlo Hydrogel Wound Dressing/Packer. The composition of AcryNoodles is substantially similar to the predicate device, AcryDerm Advanced Wound Dressing. The method of manufacturing of AcryNoodles is identical to that of the predicate device, AcryDerm Advanced Wound Dressing. AcryNoodles is a bundle of absorbent strands for placement in cavitated wounds similar to Kaltostat Wound Dressing.

Performance Characteristics: AcryNoodles Absorbent Wound Dressing is a highly absorbent device that is designed to perform like the predicate devices. Laboratory tests have shown that AcryNoodles has an identical absorbent capacity for aqueous moisture as AcryDerm. The device however absorbs moisture substantially faster than AcryDerm.

Manufacturing: AcryNoodles Absorbent Wound Dressing will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.

Bruce L. Gibbins 8-19-96